IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
(CENTRAL DIVISION)

THE UNITED STATES OF AMERICA, QUI-TAM PLAINTIFF, JAMES HEINEMAN, RELATOR,	:	**4:02-CV-40469**
Plaintiff	:	**COMPLAINT and DEMAND FOR TRIAL BY JURY**
v.		
JOHNSON & JOHNSON and CENTOCOR, INC., *DOE DEFENDANTS*	:	

COMES NOW the Plaintiff, the GOVERNMENT OF THE UNITED STATES OF AMERICA, through JAMES HEINEMAN, Relator, and states as follows:

PARTIES, JURISDICTION AND VENUE

1. Qui-Tam Plaintiff, United States of America, is the proper named party under the False Claims Act, pursuant to 31 U.S.C. §3730(b).

2. James Heineman is the relator ("Relator") who calls attention of the United States to the unlawful conduct of Defendants, Johnson & Johnson and Centocor, Inc. ("Centocor") and the individual defendants (collectively called "the Defendants") in violation of the False Claims Act, 31 U.S.C. §3729, *et. seq.*

3. Johnson & Johnson is a New Jersey corporation licensed to do business, doing business, and having an established work force in Des Moines, Polk County, Iowa.

4. Centocor is a Pennsylvania corporation licensed to do business, doing business, and having an established work force in the state of Iowa and in Des Moines, Polk County, Iowa.

5. Centocor is a wholly owned subsidiary of Johnson & Johnson and is fully controlled by Johnson & Johnson.

6. Defendants Does are individuals employed by Johnson & Johnson and Centocor who had knowledge of and participated in the events alleged in this Complaint.

7. Johnson & Johnson and Centocor are liable for the actions of the Defendant Does under the doctrine of respondeat superior.

8. Jurisdiction of this action is proper under the False Claims Act, 31 U.S.C. §3729, *et. seq.*

9. Venue of this action in this court is proper under 28 U.S.C. §1391 (b) and (c).

GENERAL ALLEGATIONS

10. Johnson & Johnson is in the business of selling pharmaceuticals. Two of its pharmaceutical products are Remicade and Retavase.

11. Centocor is a wholly owned subsidiary of Johnson & Johnson and is in the business of selling pharmaceuticals. Centocor sells Remicade and Retavase.

12. Remicade and Retavase are marketed to providers who participate in Medicare and Medicaid.

13. The defendants marketed Remicade and Retavase and engaged in improper conduct which caused false claims to be made upon the United States Government.

A. REMICADE

14. Remicade is a drug that is used in the treatment of moderate to severely active rheumatoid arthritis and in the treatment of Crohn's disease.

15. Remicade can cause severe side effects, including heightened susceptibility to tuberculosis and infections caused by fungi or bacteria, and Remicade is typically used after patients have tried other treatments and have failed to adequately respond to them. Furthermore,

because Remicade is a combination of human and mouse antibodies, many patients must also take methotrexate to prevent their immune systems from rejecting the drug.

16. Remicade is administered via intravenous infusion. It is available by prescription only, and may only be prepared and administered by a health care professional. Remicade is covered by Medicare Part B as an injectable administered directly by a health care provider.

Improper Marketing

17. The "allowed" amount to be paid for a drug under Medicare is determined under the payment methodology set forth in 42 CFR §405.517.

18. Medicare Part B carriers, third-party organizations who are contracted by the government to administer Medicare, rely upon the average wholesale price ("AWP") published in pharmaceutical industry publications (most commonly relied upon is the "Red Book") to ascertain the allowable Medicare reimbursable amount.

19. These publications rely entirely upon the manufacturers, distributors and suppliers of the listed products to accurately report the actual AWP for these products.

20. The defendants manipulated the AWP of Remicade so that it did not accurately reflect the actual cost of the drug.

21. The AWP for Remicade is substantially higher than the prices Defendant charged wholesalers and suppliers for Remicade. As a consequence, the amount that a provider is reimbursed for Remicade and the actual cost of the product differs substantially. A provider is reimbursed significantly more for the product than was paid for the product. While Medicaid reimbursement amounts may be calculated on a different basis, the "spread" between reimbursement and the acquisition cost of the product also existed under the Meicare reimbursement calculations.

22. Defendants created and marketed this profit potential to influence medical providers' decisions to prescribe Remicade instead of competing drugs.

23. The marketing scheme utilized by the Defendants was driven by marketing the significant profit or earning that could be obtained because of the gap, or the "spread," between the acquisition cost and the Medicare reimbursement rate for Remicade.

24. This marketing scheme caused false claims to be made upon the government because through this scheme Defendants influenced and/or conspired with providers to utilize Remicade based upon the profit that could be made from utilizing the drug when other less costly and effective drugs could have been utilized. Providers billed this use of Remicade to Medicare and Medicaid.

25. Defendants marketed this spread by:

(a) Training and encouraging its sales force and providing its sales force tools by which to market this spread.

(b) Hiring individuals with the position entitled "reimbursement specialists," who were instructed to work with physicians to show them how to utilize the spread. The reimbursement specialists and the immunology specialists would conduct "business reviews" for the practice. A business review can be legitimate when it encompasses key practice areas like capacity, site of care, nursing requirements, patient education, and nursing qualifications. The Defendants utilized business reviews however to demonstrate to providers what profit they were making off of the product and how to increase profits by increasing patients. Reimbursement specialists even created spreadsheets to demonstrate to providers how much money they were making off of the drug.

(c) Creating business plans for use within the Defendants' company to build an internal strategy for building business that encompassed promoting the spread to market Remicade.

26. These improper marketing concepts were taught in training classes, at business planning reviews, at sales meetings, during conference calls with the sales force, and even left in voice messages to the sales force.

27. Defendants improperly marketed "the spread" to providers creating a financial motivation to utilize Remicade instead of less costly alternatives. The improper marketing contributed to an over-utilization of Remicade and caused false claims to be made upon the United States of America.

Preceptorships

28. The Defendants also marketed the product, Remicade, by funneling money into physicians' offices through the use of preceptorships to assist physicians in acquiring infusion chairs and establishing infusion suites to allow for their administration of the drug. The infusion time required for the administration of Remicade is approximately two hours.

29. Physicians require a setting in which to administer this drug, because of the time involvement with the infusion. The physician needs to establish an area in which to perform the infusions that will not interfere with his or her practice. Generally, the physicians would set up infusion rooms, or infusion suites. These infusion suites would contain infusion chairs as well as reading material and could even have a television.

30. The initial up front cost to a provider to purchase the chairs necessary to administer Remicade and the cost of establishing an area in which patients can comfortably receive the Remicade infusion, could be an inhibiting factor in selling the product to providers.

31. The Defendants encouraged and allowed its sales force to improperly utilize preceptorships to funnel funds into providers' practices to assist the provider in creating an area in which Remicade could be administered. In some instances money from preceptorships was offered as a way to offset unfavorable insurance reimbursements.

32. Preceptorships can be a legitimate tool when utilized properly. Preceptorships occur when Centocor pays a physician to allow the sales person to work with the physician for a

day to understand when and how the physician diagnoses and treats rheumatoid arthritis or Crohn's disease or related diseases with various therapies including Remicade. A physician would typically be paid between $300 and $750 for a preceptorship. The Defendants, however, used multiple preceptorships with the same practice or physicians as a way to funnel money into providers' practices.

33. Preceptorships were used as a method to provide the provider with a kickback for utilizing Remicade. Furthermore, improper use of preceptorships was a method by which Defendants allowed physicians to utilize Remicade allowing Defendants to illegally market the spread and influence and conspire with providers to utilize Remicade over less costly alternatives. Providers billed this use of Remicade to Medicare and Medicaid.

34. Utilizing preceptorships to funnel money into practices was common practice and was even taught as appropriate and desired conduct in training courses for new sales members.

35. Preceptorships were utilized as improper kickbacks and bribes to providers and as an improper marketing tool which contributed to an over-utilization fo Remicade and caused false claims to be made upon the United States of America.

Advisory Boards

36. The Defendants marketed Remicade through the improper use of advisory boards. Advisory boards consist of physicians who are asked to participate in a weekend event during which they are asked to answer some clinical questions with regard to Remicade and other treatments for rheumatoid arthritis and Crohn's disease.

37. Advisory boards are appropriate tools for a drug company to utilize to determine how its products are being utilized in the market. The Defendants utilized advisory boards, however, as a further opportunity to market Remicade improperly.

38. The standard practice for the Defendants was to invite their top accounts to weekend events in very desirable locations. During the weekend, the physicians would sit through a brief period of questioning to fulfill their obligation as an "advisory board." Until recently, the sales force of the Defendants was actually present at these advisory board meetings. It was not uncommon for the same physicians to be invited to numerous advisory board meetings.

39. Advisory Board meetings were utilized primarily as a tool to increase business with top customers. The meetings often occurred at luxury hotels or resorts. Physicians were paid an honorarium plus travel and lodging expenses to attend, this increased the likelihood of attendance by the most sought after customers. Physician responses were often gathered and reported back to specific immunology specialists as a way to further the sales promotion with individual providers.

40. Defendants offered providers illegal kickbacks and bribes in the form of luxury weekends to improperly influence providers to utilize Remicade. Those physicians who utilized more Remicade were invited to more luxury weekends. During these weekend "meetings," Defendants influenced and conspired with providers so that providers used Remicade over less costly alternatives. Providers billed this use of Remicade to Medicare and Medicaid.

41. Advisory Boards were a pretextual method whereby the defendatns improperly marketed Remicade and also through which proivders received improper kickbacks, which contributed to an over-utilization of Remicade and caused false claims to be made upon the United States of America.

Patient Education

42. Defendants improperly marketed Remicade through the improper use of patent education programs.

43. Patient education programs can be a legitimate activity when the goal of the program is to educate patients and provide information regarding Remicade, such as its appropriate uses and its potential side effects. Defendants did work with the Arthritis Foundation to provide such legitimate programs.

44. Defendants, however, also directly paid physicians to present programs to their own patients and potential patients as a means for the physician to build is or her practice and thereby increase the utilization of Remicade.

45. These payments were an improper kickback to providers and an improper marketing tool whereby Defendants influenced and conspired with providers to utilize Remicade over less costly alternatives. Defendants' contact contributed to an over-utilization of Remicade and caused false claims to be made upon the United States of America through fraudulent claims for reimbursement for Remicade filed with Medicare and Medicaid.

Peer-to-Peer and Consultants

46. The Defendants also used improperly used peer-to-peer counseling as a method to market the "spread" on Remicade.

47. In a peer-to-peer counseling, a provider or the staff of a provider that utilized Remicade and was successful with its use in his or her practice would meet with another physician or practice who was not as experienced in the use of Remicade. The physicians or individuals that presented the peer-to-peer counseling were provided a worksheet from which to conduct their peer-to-peer consulting. Part of this worksheet required the physicians to review

the use and billing practices of the physician and examining how the provider could become more profitable in using Remicade.

48. The Defendants also targeted practice consultants. Practice consultants are independent consultants that advise providers on how to run a profitable practice. The Defendants teamed up with these consultants to promote the business advantages to using Remicade. Consultants were even asked to be speakers at a program for providers.

49. Defendants used peer-to-peer counseling and consultants as an improper method to market the "spread" and to influence and consire with providers to utilize Remicade instead of less costly alternatives. Providers billed Remicaid to Medicare and Medicaid.

50. Peer-to-peer meetings and the use of consultants were a pretextual method whereby the defendants improperly marketed which contributed to an over-utilization of Remicade and caused false claims to be made upon the United States of America.

51. Individuals who were known to aggressively market the spread, utilize preceptorships to funnel money into practices, and use peer to peer counseling and consultants were promoted within the Defendant's company.

B. RETAVASE

52. Retavase is a drug that is approved and indicated for treatment of acute myocardial infarction and is marketed and sold by the Defendants.

53. Retavase is covered by Medicare Part B and Medicaid as an injectable administered directly by a health professional.

Off-Label Promotion

54. Retavase has only been approved for the treatment of acute myocardial infarction, but clinical studies have indicated that it may be effective in the treatment of deep vein thrombosis ("DVT") and partial arterial occlusion ("PAO") as well. FDA approval has not been

obtained for these other uses of Retavase The use of a drug for a purpose not yet approved by the FDA is called "off-label" use. It is illegal for a company to market a product for which is has not yet received FDA approval, or for an "off-label" use.

55. The Defendants marketed Retavase for the off-label uses of treating DVT and PAO. Defendants marketed the drug for this use by hiring a group of employees called "Advanced Clinical Specialists ("ACS's"). The ACS's were given a legitimate product to sell but the primary purpose of this sales force was to sell Retavase off-label. The ASC's were trained to get the providers to ask about the off-label use of Retavase so that the product could be sold to the provider for that use. It is commonly known throughout the company that the primary duty of the ASC's was to sell Retavase off-label.

56. The Defendants improperly and illegally marketed Retavase for off-label use to providers who billed Medicare and Medicade for Retavase.

57. The improper marketing of Retavase caused an over-utilization of the product and caused false claims to be made upon the United States of America.

Samples

58. The Defendants also improperly marketed Retavase through the use of fraudulently billed free samples and other illegal kickbacks and bribes.

59. Retavase is often sold through a bidding process to hospitals and clinics. There are other drugs that are indicated for acute myocardial infarction and providers choose which product to prescribe based in part on the cost of the product as quoted by the sales person for the drug. The sales force for Retavase were instructed to overcome lower contract prices from competitors by offering free "kits" to providers. Kits of Retavse include one dose of the product; they are intended to be used as non-billable samples of the product. It was common practice for

the defendants to offer multiple kits of Retavase to providers to make up for a lower contract bid from a competitor.

60. The use of free samples or kits of Retavase was a method whereby the defendants improperly marketed Retavase and also through which providers received improper kickbacks, which contributed to an over-utilization of Retavase. Furthermore, the use of free samples was a method whereby a provider could submit a claim for reimbursement for an item for which he or she paid nothing. The defendants influenced and conspired with providers to cause Medicare and Medicaid to reimburse providers for items received as a free kit causing false claims to be made upon the United States of America.

FALSE CLAIMS

61. The defendants knowingly presented or caused to be presented a false or fraudulent claim for payment upon the United States Government, and conspired to defraud the Government by:

(a) Getting a false or fraudulent claim allowed or paid by improperly marketing Remicade by utilizing the "spread" as a financial incentive to induce providers to utilize Remicade;

(b) Improperly using preceptorships as kickbacks and bribes to funnel funds into providers' practices to induce or increase the use of Remicade in the practices;

(c) Improperly using advisory boards as marketing opportunities and as kickbacks and bribes to induce increased use of Remicade in providers' practices;

(d) Improperly providing financial compensation to providers for performing "educational" presentations designed to increase the provider's practice and increase the use of Remicade; and

(e) Improperly using peer-to-peer reviews and utilizing consultants as a marketing opportunity to induce increased use of Remicade.

62. The Defendants knowingly made or used, or caused to be made or used, a false record or statement to fraudulently receive payment, reimbursement or property from the Government, and conspired to defraud the Government by getting a false or fraudulent claim allowed or paid by improperly promoting the off-label use of Retavase, and by providing free kits containing Retavase as a kickback to providers, who then billed for the product to offset lower priced products from competitors.

63. The Defendants encouraged and rewarded improper conduct by promoting those individuals who engaged in the activities described above.

64. Relator brings the attention of the United States of America to the false and fraudulent claims made upon the Government by Defendants. Relator is employed by Centocor.

65. Relator's information is based upon:

(a) His personal knowledge based upon what he has personally observed and witnessed during his employ at the Defendants.

(b) Verbal communications within the company to the sales force.

(c) Written materials produced by Defendants for training meetings.

(d) Written materials created by Defendants for provider use in peer-to-peer counseling.

(e) Information from other Centecor employees.

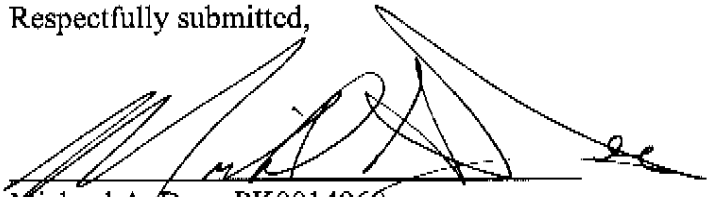
66. Defendants' conduct was willful, wanton, and in reckless disregard of the rights of the United States, entitling the United States exemplary or punitive damage.

WHEREFORE, Plaintiff, the United States of America, demands judgment against defendants for statutory civil penalties, for three times the actual damage to be proved in this action, for punitive damages, and for attorneys fees and costs.

DEMAND FOR TRIAL BY JURY

The Relator, on behalf of the United States of America, hereby demands a trial by jury in all matters alleged in this complaint.

Respectfully submitted,



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